IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

plication of

Examiner: Not Yet Assigned

Ijeoma UCHEGBU et al.

Group Art Unit: Not Yet Assigned

Application No. 10/528,602

Filing Date: September 29, 2005

For: DRUG DELIVERY

Suite 2400 1601 Market Street Philadelphia, PA 19103 Customer Number: 000110 (215) 563-4100 (telephone) (215) 563-4044 (facsimile)

Our File No. 0380-P03603US00

Certificate of Mailing Under 37 C.F.R. §1.8(a):

I hereby certify that this correspondence is being deposited on August 18, 2006 with the United States Postal Service as first-class mail in an envelope properly addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Tina M. Doyle

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

In compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants are submitting herewith a Form PTO-1449 and a copy of the references listed thereon. This Supplemental Information Disclosure Statement is being filed more than three months after the filing date of the application. However, Applicants have not yet received an action on the merits of the application. Accordingly, Applicants believe that no fee is required pursuant to 37 C.F.R. §1.97 (b) (3). In the event a fee is required, the Commissioner is authorized to charge the required fees to Deposit Account No. 04-1406. A duplicate copy of this sheet is

U.S. Patent Application No. 10/528,603

included for fee processing, if necessary.

This submission is not an admission that the references listed on the attached Form PTO-1449 constitute prior art against the claims of this application.

The Examiner is respectfully requested to confirm receipt and consideration of the cited references by initialing and returning a copy of the attached Form PTO-1449 in accordance with MPEP §609.

Applicants respectfully request full and proper consideration of the listed information during examination of the application, and that the listed information be printed on any patent that issues therefrom.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN A Professional Corporation Attorneys for Applicant(s)

Patrick J. Hagan

PTO Registration No. 27,643

Enclosures - Form PTO-1449

Copies of references listed on PTO - 1449

INFORMATION DISCLOSURE STATEMENT

SHEET

OF 2

Application Number: 10/528,602

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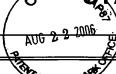
First Named Inventor: Ijedma UCHEGBU

Complete if known

Group Art Unit: Not Yet Assigned

Examiner Name: Not Yet Assigned

Our File No. 0380-P03603US00



UNITED STATES PATENT DOCUMENTS				
EXAMINER'S INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE MM-DD-YYYY	FIRST NAMED INVENTOR
	A1			
	A2			
	А3		-	
	A4			

FOREIGN PATENT DOCUMENTS					
EXAMINER'S INITIALS	CITE NO.	DOCUMENT NUMBER	COUNTRY OR REGION	DATE OF PUBLICATION MM-DD-YYYY	FIRST NAMED INVENTOR OR APPLICANT
	B1				
	B2				
	B3				
	B4				

OTHER PRIOR ART - NON-PATENT DOCUMENTS			
EXAMINER'S INITIALS	CITE NO.	Include name of the author (in Capital Letters), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
	C1	DUNN, C.J., WAGSTAFF, A.J., PERRY, C.M., PLOSKER G.L., GOA, K.L., <i>Cyclosporin - An Updated Review of the Pharmacokinetic Properties, Clinical Efficacy and Tolerability of a Microemulsion-Based Formulation Neoral R(1) in Organ Transplanation</i> , Drugs, <u>61</u> : 1957-2016 (2001)	
	C2	PORTER, C.J.H., CHARMAN, W.N., <i>In Vitro Assessment of Oral Lipid Based Formulations</i> , Advanced Drug Delivery Reviews, <u>50</u> : S127-S147 (2001)	
	СЗ	BALANDRAUD-PERI, N., QUENEAU, P.E., CAROLI-BOSC, F.X., BERTAULT-PERES, P., MONTET, A.M., DURAND, A., MONTET, J.C., Effects of Tauroursodeoxycholate Solutions on Cyclosporin and Bioavailability in Rats, Drug Metabolism and disposition, <u>25</u> : 912-916 (1997)	

EXAMINER'S	DATE	
SIGNATURE	CONSIDER	RED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw a line through citation if citation not in conformance and reference not considered. Include a copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT

SHEET

OF 2

Complete if known	
Application Number: 10/528,602	
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First Named Inventor: Ijedma UCHEGBU	-
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Examiner Name: Not Yet Assigned	
Our File No. 0380-P03603US00	

C4	GUO, J.X., PING, Q.N., CHEN, Y., Pharmacokinetic Behaviour of Cyclosporin A in Rabbits by Oral Administration of Lechithin Vesicle and Sandimmum Neoral, International Journal of Pharmaceutics, 216: 17-21 (2001)
C5	PORTER, C.J.H., CHARMAN, S.A., WILLIAMS, R.D., BAKALOVA, M.B., CHARMAN, W.N., Evaluation of Emulsifiable Glasses for the Oral Administration of the Cyclosporin in Beagle Dogs, International Journal of Pharmaceutics, 141: 227-237 (1996)
C6	LEIGH, M., HOOGEVEST, P.V., TIEMIESSEM, H., Optimising the Oral Bioavailability of the Poorly Water Soluble Drug Cyclosporin A Using Membrane Lipid Technology, Drug Delivery and Sciences, 1: 73-77 (2001)
C7	MIYAKE, K., ARIMA, H., IRIE, T., HIRAYMA, F., UEKAMA, K., Enhanced Absorption of Cyclosporin A by Complexation with Dimethyl-Beta-cyclodextrin in Bile duct-cannulated and Non-Cannulated Rats, Biological and Pharmaceutical Bulletin, 22: 66-72 (1999)
C8	BONDUELLE, S., CARRIER, M., PIMIENTA, C., BENOIT, J.P., LENAERTS, B., Tissue Concentration of Nanoencapsulated Radiolabelled Cyclosporin Following Peroral Delivery in Mice or Opthalmic Application ni Rabbits, European Journal of Pharmaceutics and Biopharmaceutics, 42: 31-319

EXAMINER'S	DATE	
SIGNATURE	 CONSIDERED	